

## **PSJ1 Exh 16**

Chunderlik Exhibit

2

3/8/21 Carrie Campbell, RDR

exhibitsticker.com



# Pharmacy Compliance

By George Chunderlik

## Pharmacy Board Review 2013

# Required Legal Education

---

- HIPAA Privacy
- HIPAA Security
- HiTech Act
- MethGuard
- Fraud, Waste & Abuse (annual)
- OSHA (annual)



# Additional Required Education

---

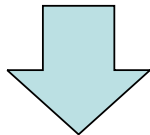
- TIRF REMS Education
- Isotretinoin Risk Mgt. (*iPLEDGE*)
- DEA Audit – What the Pharmacist Needs to Know
- Point of Sale Policy Review
- Giant Eagle Specialty Pharmacy



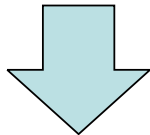
# Learning Resource Center

---

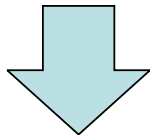
GE Central



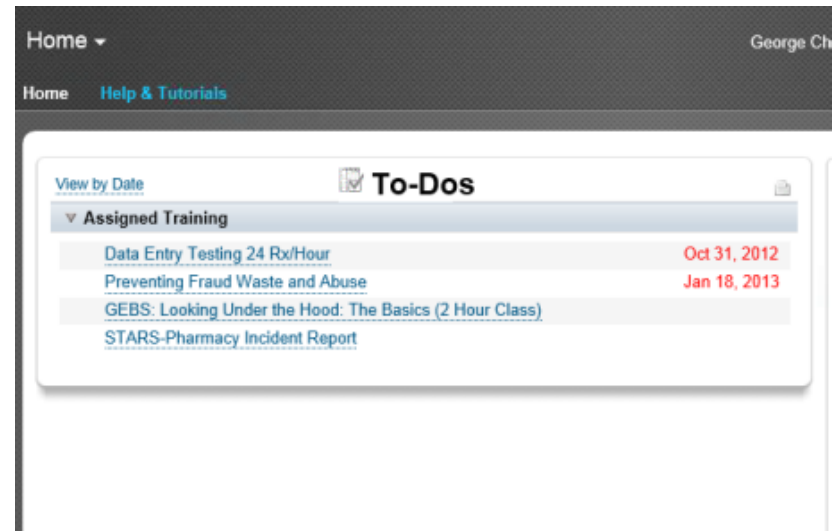
MyHRConnection



My Resources



“Enter Here” on Talent Development Logo



# First Assignment

---

- Access the Learning Resource Center to check e-learning profile
- Send an email to George Chunderlik
  - Verify completion of all legally required legal education
  - Add additional CBTs to e-learning profile

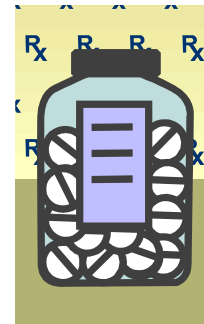
[George.Chunderlik@gianteagle.com](mailto:George.Chunderlik@gianteagle.com)



# Return to Stock

---

- Purpose
  - Establish procedures to return medications to stock from Will Call
- Procedure
  - A report will be generated daily listing medications to be removed from the will call and returned to stock
  - Will call bin is reviewed manually weekly
  - Prescriptions are credit returned
  - The bottle is labeled with the NDC of the contents and HIPAA information is blacked out then placed on the shelf to be re-dispensed within the legal time limitation
    - PA – 6 months
    - OH – 90 days
    - MD – 1 year
    - WV – 30 days



# Outdate, Damage and Recall Return Policy

---

- Purpose
  - To ensure that outdated and/or damaged product is pulled from active inventory
- Procedure
  - Each Team Member is assigned a section of the inventory to check for expiring product and clean the shelves
  - All product expiring the current month or following two months (expiring within 90 days) is removed from active inventory
  - Damaged or recalled products are removed from active inventory as discovered/notified
  - Removed products are counted and the on-hand qtys. are updated in the computer
  - Amber bottles must have the patient information blackened out
  - Removed products are returned once per quarter via our return service provider





# State Laws, Rules & Regulations

---

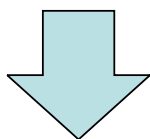
- Each pharmacist is responsible for knowing and abiding by all federal and state rules and regulations.
- Available resources are found on GE Central which include:
  - State Board Websites
    - Links to additional information governing specific areas of practice
  - Federal Websites
    - Drug Enforcement Agency (DEA)
    - FDA



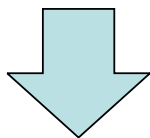
# State Laws, Rules & Regulations

---

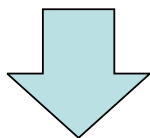
**GE Central**



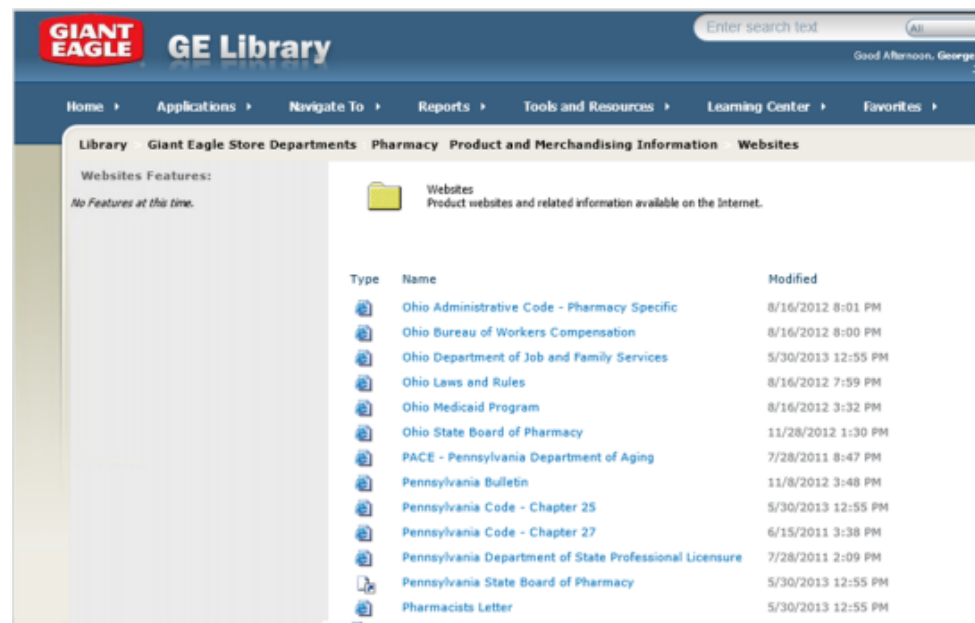
**View Pharmacy  
Library**



**Product & Merchandising  
Info**



**Websites**



HBC\_MDL00190998

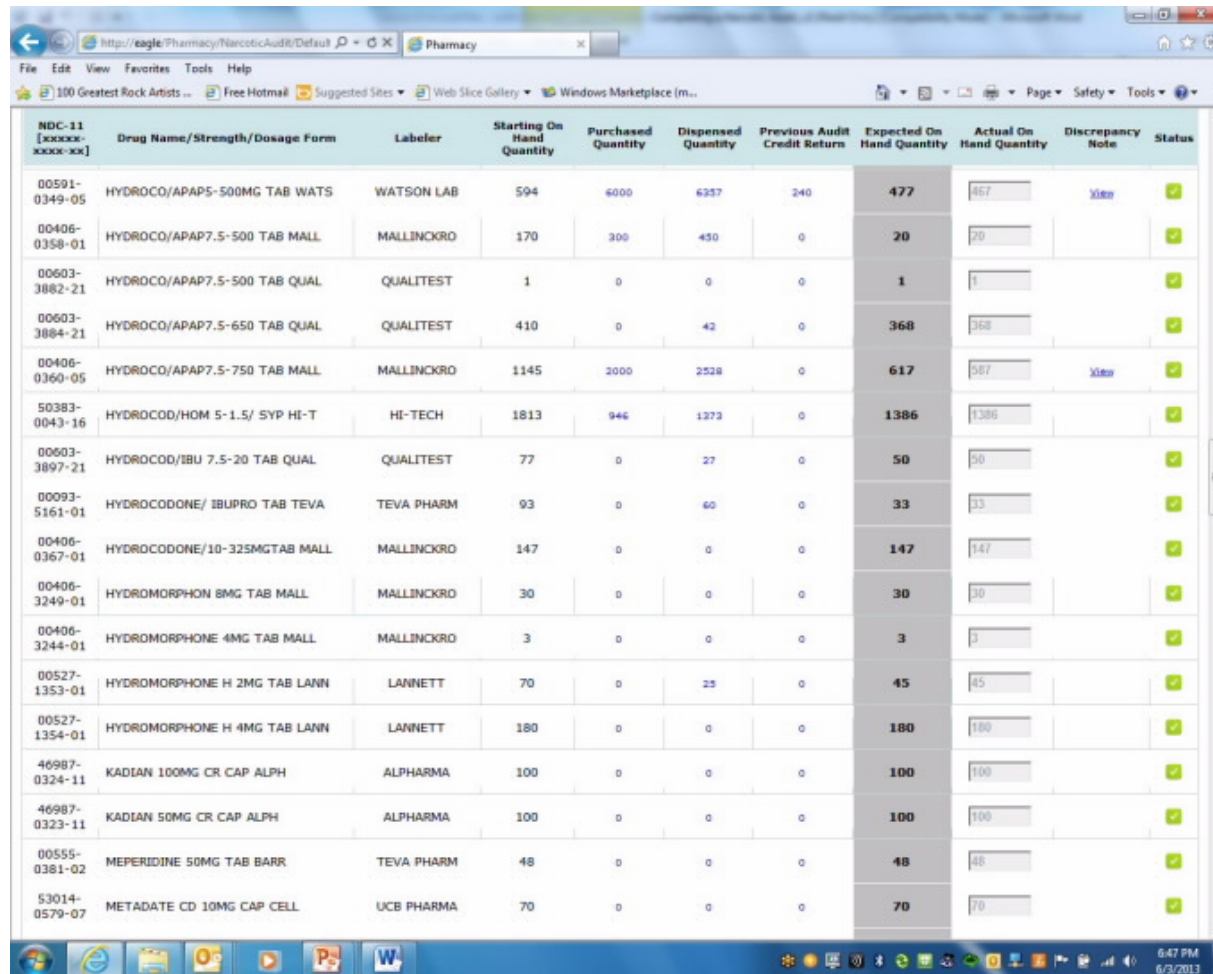
# Controlled Drug Audits

---

- Required to be completed every month
  - Exact count of all schedule II narcotics
  - Hydrocodone containing products
  - Suboxone products
  - Inventory is tracked by NDC rather than medication name (GPI) making it easier to identify reasons for discrepancies.



# Controlled Drug Audits



NDC-11 [xxxx-xxxx-xx]	Drug Name/Strength/Dosage Form	Labeler	Starting On Hand Quantity	Purchased Quantity	Dispensed Quantity	Previous Audit Credit Return	Expected On Hand Quantity	Actual On Hand Quantity	Discrepancy Note	Status
00591-0349-05	HYDROCO/APAP5-500MG TAB WATS	WATSON LAB	594	6000	6337	240	477	467	<a href="#">View</a>	✓
00406-0358-01	HYDROCO/APAP7.5-500 TAB MALL	MALLINCKRO	170	300	450	0	20	20		✓
00603-3882-21	HYDROCO/APAP7.5-500 TAB QUAL	QUALITEST	1	0	0	0	1	1		✓
00603-3884-21	HYDROCO/APAP7.5-650 TAB QUAL	QUALITEST	410	0	42	0	368	368		✓
00406-0360-05	HYDROCO/APAP7.5-750 TAB MALL	MALLINCKRO	1145	2000	2528	0	617	587	<a href="#">View</a>	✓
50383-0043-16	HYDROCOD/HOM 5-1.5/ SYP HI-T	HI-TECH	1813	946	1273	0	1386	1386		✓
00603-3897-21	HYDROCOD/IBU 7.5-20 TAB QUAL	QUALITEST	77	0	27	0	50	50		✓
00093-5161-01	HYDROCODONE/ IBUPRO TAB TEVA	TEVA PHARM	93	0	60	0	33	33		✓
00406-0367-01	HYDROCODONE/10-325MG TAB MALL	MALLINCKRO	147	0	0	0	147	147		✓
00406-3249-01	HYDROMORPHON 8MG TAB MALL	MALLINCKRO	30	0	0	0	30	30		✓
00406-3244-01	HYDROMORPHONE 4MG TAB MALL	MALLINCKRO	3	0	0	0	3	3		✓
00527-1353-01	HYDROMORPHONE H 2MG TAB LANN	LANNETT	70	0	25	0	45	45		✓
00527-1354-01	HYDROMORPHONE H 4MG TAB LANN	LANNETT	180	0	0	0	180	180		✓
46987-0324-11	KADIAN 100MG CR CAP ALPH	ALPHARMA	100	0	0	0	100	100		✓
46987-0323-11	KADIAN 50MG CR CAP ALPH	ALPHARMA	100	0	0	0	100	100		✓
00555-0381-02	MEPERIDINE 50MG TAB BARR	TEVA PHARM	48	0	0	0	48	48		✓
53014-0579-07	METADATE CD 10MG CAP CELL	UCB PHARMA	70	0	0	0	70	70		✓



# Pseudoephedrine (PSE) Monitoring

## Pseudoephedrine Limits (in GRAMS)

Pharmacy Selling Limits				Customer Purchase Limits		
WV: review daily, rolling 30 day, and rolling year purchase history Ohio: review daily and rolling 30 day purchase history						
State	Daily	Rolling 30 days	Rolling Year	Daily	Rolling 30 days	Rolling Year
WV	3.6	7.2	48	3.6	7.2	48
OH	3.6	9		3.6	9	
PA	3.6				9	
MD	3.6				9	



# Pseudoephedrine (PSE) Monitoring

---

- Pennsylvania and Maryland currently use manual log book to monitor and record sales
- WV and Ohio electronically track sales of PSE products via the National Precursor Log Exchange (NPLEX)
  - WV accesses Appriss web portal directly
  - OH stores utilize POS system
  - All stores anticipated to be utilizing POS to electronically track PSE sales by the end of the calendar year.

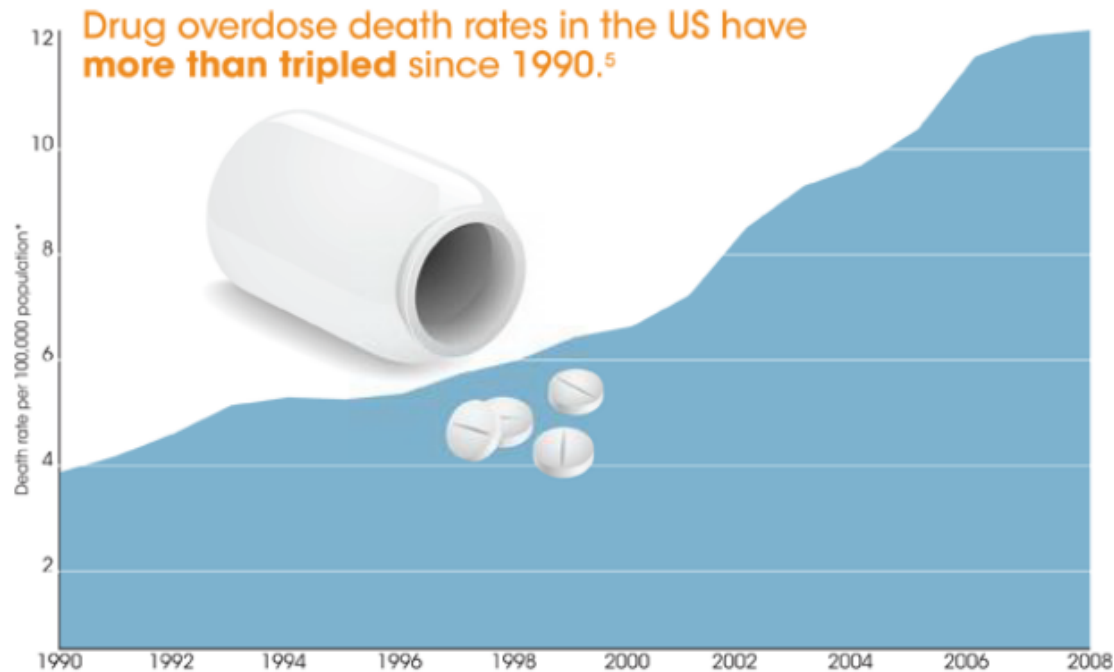


# Prescription Drug Abuse Epidemic

---

- According to the Centers for Disease Control (CDC)

100 people die from drug overdoses every day in the United States.<sup>4</sup>



\*Deaths are those for which poisoning by drugs (illicit, prescription, and over-the-counter) was the underlying cause.



# Prescription Drug Abuse Epidemic

---

- In 2009 deaths from prescription drug overdoses exceed deaths from auto accidents for the first time ever
- Over 20% of Americans admit to abusing prescription drugs
- Prescription drugs are now the recognized gateway drugs to “heroin” and other illegal drugs





# Controlled Substance Dispensing Statement of Purpose

---

- It is our responsibility both as healthcare professionals and as a company to do all we can to curb the misuse of prescription drugs
- The DEA in its efforts to control the illegal use of prescription drugs is holding pharmacists *personally* accountable for their decisions and actions when dispensing controlled substances.



# Corresponding Responsibility

---

- Prescribers have a duty to write prescriptions both legally and responsibly
- Pharmacists have an acknowledged **corresponding responsibility** to “exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription”



# Due Diligence

---

- Verify the prescription is valid and written in the usual course of professional treatment
  - Phone book, internet site, operator assistance
- The prescription is appropriate (dosage and quantity are reasonable for the patient's diagnosis)
  - Large dosages and/or quantities are indicators for misuse
  - If applicable record the reason for the high dose on the rx
- The prescription is timely (on schedule to be filled based on previous prescription history)
  - Early refills and multiple doctors are signs for misuse



# Due Diligence con't

---

- Verify the prescribers DEA registration
  - Use the formula to validate DEA number
- Access the information within the state's Prescription Drug Monitoring Program (PDMP) if available
  - OARRs in Ohio
- Review prescription for alterations/changes
- Request diagnosis, treatment plans, patient contract

**DOCUMENT! DOCUMENT! DOCUMENT!!!!**



# Promise of Support

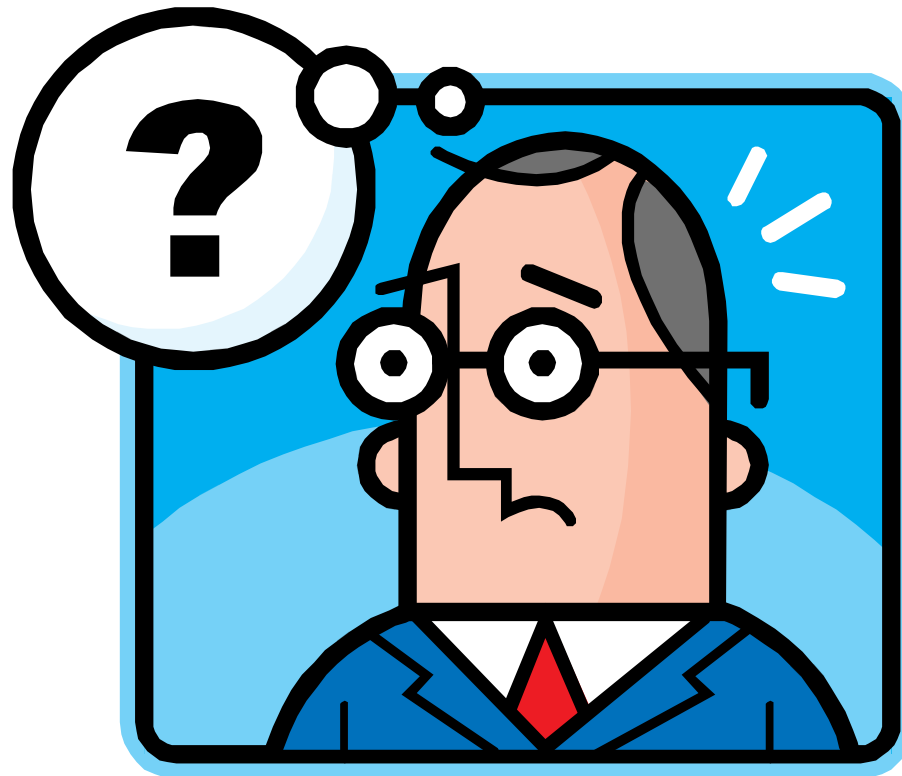
---

- Giant Eagle supports the professional judgment of each Pharmacist Team Member
- If after performing required due diligence, any pharmacist refuses to fill a prescription for a medication due to concerns of validity and/or misuse, Giant Eagle will support the decision



# Questions

---



# Congratulations & Good Luck

---



HBC\_MDL00190998